NEWS RELEASE

Moderna Submits Amendment to the Emergency Use Authorization for an Additional Booster Dose of its COVID-19 Vaccine in the U.S.

3/17/2022

CAMBRIDGE, MA / ACCESSWIRE / March 17, 2022 / Moderna, Inc. (NASDAQ:MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced that it has submitted a request to the U.S. Food and Drug Administration (FDA) for an amendment to the emergency use authorization (EUA) to allow for a fourth dose of its COVID-19 vaccine (mRNA-1273) in adults 18 years of age and older who have received an initial booster of any of the authorized or approved COVID-19 vaccines. The request to include adults over 18 years of age was made to provide flexibility for the U.S. Centers for Disease Control and Prevention (CDC) and healthcare providers to determine the appropriate use of an additional booster dose of mRNA-1273, including for those at higher risk of COVID-19 due to age or comorbidities. This submission is based in part on recently published data generated in the United States and Israel following the emergence of Omicron.

The U.S. FDA **approved** the Biologics License Application (BLA) for SPIKEVAX (COVID-19 Vaccine, mRNA) to prevent COVID-19 in individuals 18 years of age and older on January 31, 2022. Moderna's COVID-19 vaccine was previously available under EUA in the U.S. from December 18, 2020. A booster dose of the Moderna COVID-19 vaccine at the 50 µg dose level is **authorized** for emergency use in the U.S. under EUA for adults 18 years and older. A third dose of the Moderna COVID-19 vaccine at the 100 µg dose level is authorized for emergency use in immunocompromised individuals 18 years of age or older in the United States who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

Moderna continues to collect and monitor real-world data on its COVID-19 vaccine. Real-world evidence continues to confirm the effectiveness and robust safety profile of the Moderna COVID-19 vaccine. Clinical trials are ongoing for Moderna's Omicron-specific booster (mRNA-1273.529) and a bivalent Omicron-specific booster (mRNA-1273.214).

INDICATION (U.S.)

SPIKEVAX (COVID-19 Vaccine, mRNA) is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

IMPORTANT SAFETY INFORMATION

- Do not administer to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine.
- Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccine.
- Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. The observed risk is highest in males 18 through 24 years of age.
- Syncope (fainting) may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.
- Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished response to the vaccine.
- The vaccine may not protect all vaccine recipients.
- Adverse reactions reported in clinical trials following administration of the vaccine include pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, axillary swelling/tenderness, fever, swelling at the injection site, and erythema at the injection site, and rash.
- The vaccination provider is responsible for mandatory reporting of certain adverse events to the Vaccine Adverse Event Reporting System (VAERS) online at **https://vaers.hhs.gov/reportevent.html** or by calling 1-800-822-7967.
- Please see the **SPIKEVAX Full Prescribing Information** . For information regarding authorized emergency uses of the Moderna COVID-19 Vaccine, please see the **EUA Fact Sheet** .

About Moderna

In over 10 years since its inception, Moderna has transformed from a research-stage company advancing programs

in the field of messenger RNA (mRNA), to an enterprise with a diverse clinical portfolio of vaccines and therapeutics across seven modalities, a broad intellectual property portfolio in areas including mRNA and lipid nanoparticle formulation, and an integrated manufacturing plant that allows for rapid clinical and commercial production at scale. Moderna maintains alliances with a broad range of domestic and overseas government and commercial collaborators, which has allowed for the pursuit of both groundbreaking science and rapid scaling of manufacturing. Most recently, Moderna's capabilities have come together to allow the authorized use and approval of one of the earliest and most effective vaccines against the COVID-19 pandemic.

Moderna's mRNA platform builds on continuous advances in basic and applied mRNA science, delivery technology and manufacturing, and has allowed the development of therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases, cardiovascular diseases and auto-immune diseases. Moderna has been named a top biopharmaceutical employer by Science for the past seven years. To learn more, visit **www.modernatx.com**.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including regarding: the potential authorization under an EUA for administration of a fourth dose of the Company's COVID-19 vaccine (mRNA-1273) by the U.S. FDA; the effectiveness and safety of mRNA-1273; and ongoing clinical trials for mRNA-1273.529 and mRNA-1273.214. The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond Moderna's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. These risks, uncertainties, and other factors include those other risks and uncertainties described under the heading "Risk Factors" in Moderna's most recent Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) and in subsequent filings made by Moderna with the SEC, which are available on the SEC's website at **www.sec.gov**. Except as required by law, Moderna disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on Moderna's current expectations and speak only as of the date hereof.

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